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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,811	09/30/2004	Graham Leslie Aldous	2864-1-001	8304

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EXAMINER	
KOSINSKI, IRINA Y	

ART UNIT	PAPER NUMBER
4131	

MAIL DATE	DELIVERY MODE
05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,811	ALDOUS ET AL.	
	Examiner	Art Unit	
	IRINA KOSINSKI	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/22/2008, 11/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

References EP0026252, WO01/22930, JP1090165, JP726837 were not considered since no translation was submitted on the IDS of 11-25-2005.

Specification

1. The disclosure is objected to because of the following informalities: page 5, line 12 sites J. Clinical Periodontology (1994), 21, 431-443. The article is on pages 431-437.

2. Page 16, line 6 discloses a mathematically significant difference "p" between the results of the study, but there is no explanation on how "p" was calculated. Appropriate corrections are required.

3. The use of the trademarks CETEARETH 30® (page 9, line 12) and PERIDEX® (page 15 of the specification, and Figure 2 - drawings) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims

are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 25-47 have been renumbered 24-46.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 24-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dentaid (European Patent Application # EP 0920857A2), in view of Peterson et al. (US Patent # 5370864) and in further view of Hill (US Patent # 5993784) and Ananthapadmanabhan et al. (US Patent # 6045817).

6. Claim 24 of the instant application discloses an oral formulation comprising chlorhexidine or a salt thereof, a zinc salt, masking and/or flavouring agents, including sweetening agents, and other conventional components of oral formulation.

7. Claims 30-32 disclose the use of one or more gluconate salts, wherein zinc salt is zinc gluconate, and chlorhexidine salt is a chlorhexidine digluconate. Claim 34 recites the use of chlorhexidine diacetate.

8. Claim 1 of Dentaid application discloses an oral composition comprising chlorhexidine digluconate or other pharmaceutically acceptable chlorhexidine salt, and a pharmaceutically acceptable salt of Zn (+2). The reference encompasses claims 24,

30-32, and 34 of the instant application insofar that it discloses the use of pharmaceutically acceptable chlorhexidine salts and zinc salt as essential components of the oral composition.

9. Claims 25- 26 of the instant application disclose the use of saccharine sodium as sweetening agent with concentration up to 0.05% (w/w), which falls into a window of concentration for saccharine (0.005-0.10% (w/w)), disclosed in claim 5 of Dentaid application. This reference, however, does not teach the use of a second sweetening agent, described in claim 24 of the instant application.

10. Claim 2 of Peterson et al. discloses the use of artificial sweeteners selected from the group of sodium salt of saccharin, neohesperidine dihydrochalcone and mixtures thereof. Column 3, line 26 of the reference patent teaches the use of one or more of these sweetener types, which encompasses claim 24 of the instant application.

11. Claim 27 discloses concentration of neohesperidine dihydrochalcone (up to 0.1% (w/w)). Claims 35-36 of the instant application describe the use of masking and/or flavoring agents selected from flavoring oils and methyl salicylate, where the concentration of said agents is from 0.1% to 5% (w/w). Claim 37 describes the components, such as fluoride materials, dentally acceptable abrasive materials, surfactants, thickeners, etc.

12. Claim 1 of Hill's patent discloses a toothpaste comprising: abrasives, humectants, water, surfactant, anti-caries agent. Claim 7 of Hill's patent recites the use of thickeners or gelling agents, anticipating claim 37 of the instant application. Claim 8

of Hill's patent describes the use of flavoring and/or sweetening agents at from 0.01% to 5% by weight, which anticipates claims 27, 35-36 of the instant application.

13. The three references combined teach all the limitations of claims 24-27, 30-32, and 34-37.

14. The motivation to combine sweeteners would have been obvious to the person skilled in the art after studying the properties of chlorhexidine and neohesperidine dihydrochalcone. The sweetener is known in the art to have a slow taste onset and a lingering aftertaste ("Dihydrochalcone sweeteners. Synthesis and sensory evaluation of sulfonate derivatives" by DuBois et al., Journal of Agricultural and Food Chemistry, 1977, 25(4), page767, figure 1). Chlorhexidine digluconate is known in the art as having its effect over a long period of time (page 3, line 18 of Dentaid patent application). It is also known in the art as having a bitter taste ("Reduction of saltiness and bitterness after a chlorhexidine rinse" by Breslin et al., Chemical Senses Journal, 26, pages 105-116, 2001). It makes perfect sense to combine this ingredients in an oral formulation to provide a pleasant taste that starts working later then the conventional sweetener (saccharin sodium in this case), and has a lingering aftertaste to make product more tolerable by patients using chlorhexidine digluconate oral formulation. Claims 28-29, and 33 of the instant application disclose concentrations of chlorhexidine or a salt thereof (0.1 to 1.0% (w/w)), narrowing it down further to about 0.6% (w/w) of chlorhexidine digluconate, and zinc salt (0.1 to 1.0% (w/w)).

Page 5, example 1 of Stafford-Miller Ltd. exhibits mouthwash formulation ingredients and their concentrations: chlorhexidine gluconate – 0.5647% (w/w), and

Zinc gluconate – 0.84% (w/w), encompassing claims 28-29, and 33 of the instant application.

15. Claims 41, 43-45 disclose the use of non-ionic and zwitterionic surfactants in combination, wherein the range of said surfactants is from 0.1 to 10% (w/w), with the optimal concentration being about 1.7% (w/w). The ratio of the non-ionic surfactant to zwitterionic surfactant is about 2.4 to 1 by weight.

16. Claim 1 of the Ananthapadmanabhan et al. discloses the use of zwitterionic and non-ionic surfactants in combination, which encompasses claim 41 of the instant application. It also discloses the ranges for a zwitterionic surfactant (0.2 to about 5 wt %), and a non-ionic surfactant (0 to about 10 wt %), encompassing claims 43-45 of the instant application.

17. Claims 38 and 40 of the instant application disclose the use of surfactants, which are selected from non-ionic and zwitterionic surfactants; zwitterionic surfactants selected from the group of betaines and alkylamido alkyl amines.

18. Paragraph 28, page 3 of Dentaid's application describes the use of non-ionic or amphoteric (zwitterionic) surface-active agents, selected from propyl betaine cocamide and the like. This encompasses claims 38 and 40 of the instant application.

19. Claims 39 and 42 of the instant application disclose the use of macrogol ether and cocamidopropyl betaine as surfactants of the oral formulation.

20. Claim 3 of Dentaid's application discloses the use of propyl betaine cocamide as an amphoteric surface-active agent. It also discloses non-ionic agents, selected from the groups of polyoxyethylene esters, etc. Macrogol ether is a condensation product of

polyethylene glycol and fatty alcohols, and is an obvious variant of the groups described by Dentaid.

21. Claim 46 is depended on claim 24, further limiting an oral composition in such a way that it could be a toothpaste, a dentifrice, a mouthwash, etc. It would be obvious to a person skilled in the art to make a toothpaste, or a dentifrice, or a mouthwash comprising an oral composition of claim 24 to make it available for patients with different preferences.

22. Claims 24-46 are rejected.

23. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IRINA KOSINSKI whose telephone number is (571)270-1334. The examiner can normally be reached on Monday through Friday 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/IRINA KOSINSKI/
Examiner, Art Unit 4131

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4131